

K072059

**SMITHS MEDICAL MD, INC.
510(k) Premarket Notification**

**GRIPPER® Micro Needle
510(k) Summary**

NOV - 1 2007

I. Applicant (Sponsor) Name and Address

Smiths Medical MD, Inc.
1265 Grey Fox Road
St. Paul, MN 55112
Establishment Reg. No.: 2183502

II. Contact Name and Phone

Brian Haugstad
Senior Regulatory Affairs Associate
Company Phone: (651) 628-7513
Company Fax: (651) 628-7457

III. Device Trade/Proprietary Name

GRIPPER® Micro Needle

IV. Device Classification/Common Name/Panel

Administration Set

21 CFR Reference: §880.5440
21 CFR Common Name: Intravascular Administration Set
Classification: Class II
Product Code: FPA
Review Panel: General Hospital

V. Identification of Predicate Device

The Smiths Medical MD, Inc. GRIPPER® Micro needle is substantially equivalent to the Smiths Medical MD, Inc. GRIPPER PLUS® needle.

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VI. Device Description

The GRIPPER® Micro needle is comprised of the inserter and the infusion site with extension tubing and a standard luer fitting; there are versions either with or without needless access connector y-site. The inserter incorporates a sharp trocar needle and retractor arm. The infusion site incorporates a small septum and an attached blunt cannula. Fully assembled, the inserter and infusion site are combined with the trocar needle inserted through the septum and cannula. After insertion of the cannula and trocar into the implanted port, the inserter retractor arm is activated removing the trocar needle from the cannula and infusion site septum leaving the blunt cannula in the implanted port. The trocar needle tip is captured in the inserter to prevent needle stick injury, and the inserter is discarded. Upon removal of the infusion site from the implanted port, the blunt cannula is designed to further prevent needle stick injury that may result from rebounding action during infusion site extraction.

VII. Intended Use of the Device

The GRIPPER® Micro needle is designed for the administration into or withdrawal of fluids from implanted ports.

VIII. Indications for Use

The GRIPPER® Micro needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against accidental needlestick injuries.

IX. Summary of Studies

A. Functional Testing

The GRIPPER® Micro needle met all established acceptance criteria for performance testing and design verification testing.

B. Clinical Studies

Clinical studies for the GRIPPER® Micro needle was deemed not necessary due to its similarity in materials, design and function to current Smiths Medical MD, Inc. devices.

C. Conclusions Drawn from the Studies

Based upon the information provided; the GRIPPER® Micro needle meets all acceptance criteria for performance testing and design verification testing. Therefore, this product is considered acceptable for human use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2007

Mr. Brian L. Haugstad
Senior Regulatory Affairs Associate
Smiths Medical MD, Incorporated
1265 Grey Fox Road
Saint Paul, Minnesota 55112

Re: K072059

Trade/Device Name: GRIPPER[®] Micro Needle
Regulation Number: 21 CFR 880.5540
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 12, 2007
Received: October 15, 2007

Dear Mr. Haugstad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SMITHS MEDICAL MD, INC.
510(k) Premarket Notification

GRIPPER[®] Micro Needle
Indications for Use

510(k) Number (if known): TBD

K072059

Device Name: GRIPPER[®] Micro Needle

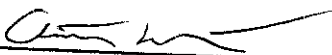
Indications for Use:

This product is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against accidental needlestick injuries.

Prescription Use X OR Over-The Counter Use Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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